

REMARKS

Reconsideration of the present application is requested in view of the foregoing amendments and following remarks.

I. **Amendments to the Claims**

Claim 1 is canceled without prejudice or disclaimer. Applicants reserve the right to pursue the canceled subject matter in a future application.

Claim 2 is amended to delete part (h), to identify BGL6 as a β -glucosidase, and to add a period.

New claims 39-43 have been added. Support for new independent claim 39 can be found, e.g., in original claim 2(h). Support for new dependent claims 40-43 can be found, e.g., in original claim 2.

Claim 4 is amended to change its dependency to new claim 39.

Claim 19 is amended to delete language relating to β -glucosidase activity and to insert a space between "claim" and "2."

No new matter has been added by these amendments.

II. **Objections to the Specification**

The Examiner noted that the application does not include the necessary reference to the priority document.

The specification has been amended to comply.

The Examiner requested that the specification be amended to remove hyperlinks.

The specification has been amended to comply.

III. **Rejection under 35 U.S.C. § 112, first paragraph (written description)**

Claims 1-17, 19, and 20 were rejected under 35 U.S.C. § 112, first paragraph, as not being supported by an adequate written description for a variant polypeptide having β -glucosidase activity or a polynucleotide relating to such a polypeptide.

The rejection is traversed in view of the foregoing amendments and following remarks.

Claim 1 has been canceled, obviating the rejection of this claim.

Claims 2 and 19 have been amended to delete language relating to β -glucosidase activity. Claim 2 has further been amended to delete the language of part

(h) of the claim, which now appears as new claim 39. Applicants submit that these amendments obviate the rejection, particularly in view of the USPTO's Written Description Training Materials published on March 25, 2008.

Example 11 (page 37) of the Training Materials relates to claims that recite percent identity to a reference sequence. In particular, exemplary claims 1 and 2 read:

Claim 1. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2.

Claim 2. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2; wherein the polypeptide has activity X.

According to the Training Materials, Claim 1 satisfies the written description requirement because, in the absence of a functional limitation, even if there is no teaching regarding the 15% of amino acids that vary from SEQ ID NO: 2, the description of SEQ ID NO: 2 in combination with what is known in the art would put one skilled in the art in possession of the invention. Only claim 2 fails to satisfy the written description requirement because of an alleged lack of structure-function correlation.

Example 6 (page 22) of the Training Materials relates to claims that recite hybridization language. In particular, exemplary claim 3 reads:

Claim 3. An isolated nucleic acid that encodes a protein that binds to the NDG receptor and stimulates tyrosine kinase activity, wherein the nucleic acid hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1.

According to the subsequent analysis:

The disclosure of SEQ ID NO: 1 combined with the knowledge in the art regarding hybridization would put one in possession of the genus of nucleic acids that would hybridize under stringent conditions to SEQ ID NO: 1. However, without a recognized correlation between structure and function, those of ordinary skill in the art would not be able to identify without further testing which of those nucleic acids that hybridize to SEQ ID NO: 1 would also encode a polypeptide that binds to NDG receptor and stimulates tyrosine kinase activity. Thus, those of ordinary skill in the art would not consider the applicant to have been in possession of the claimed genus of nucleic acids based on the single species disclosed.

It is clear from this analysis that *only* the functional language recited in the exemplary claim, and *not* the hybridization language, raise a written description issue.

As amended, the pending claims are drawn to a polypeptide having at least 85% sequence identity to the amino acid sequence presented in Figure 2 (SEQ ID NO:2), and to a polynucleotide encoding (or complementary to a polynucleotide encoding) such a polypeptide (e.g., claim 2), and to a nucleic acid sequence that hybridizes, under high

stringency conditions to the sequence presented as SEQ ID NO:3, or the complement thereof (e.g., new claim 39). Thus, pending claim 2 is now analogous to exemplary claim 1 in Example 11 and pending new claim 39 is analogous to exemplary claim 3 in Example 6 but *without* the functional language that gave rise to the written description issue. Applicants submit that the pending claims should, therefore, satisfy the written description requirements based on the USPTO's own Training Materials.

New dependent claims 40 and 41 are drawn to a subset of the sequences recited in claim 2, and are adequately described for similar reasons. New dependent claims 42 and 43 are drawn to the exemplified sequences, which are expressly described in the specification.

Withdrawal of the rejection is respectfully requested.

III. Rejection under 35 U.S.C. § 112, first paragraph (enablement)

Claims 1-17, 19, and 20 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for a variant or fragment of the claimed polypeptide or polynucleotide encoding them, and expression vectors and host based on such a polynucleotide.

Claim 1 has been canceled and claim 2 has been amended to delete language relating to a fragment, obviating parts of the rejection. Part (h) of claim 2 is now presented as new independent claim 39.

The remaining parts of the rejection are traversed because, just as the skilled person would recognize that the present polypeptides and polynucleotide variants were adequately described in the specification, the skilled person would also recognize that the specification adequately enables making and using such variants, which requires no more guidance than making and using the expressly disclosed amino acid sequence of SEQ ID NO:2 or nucleic acid sequence of SEQ ID NO:3, for which there is abundant support in the specification. The Examiner's distinction between the expressly disclosed sequences and the variants is artificial because the variants can be made and used in the same way as the disclosed sequences. Therefore, no additional disclosure is required. Moreover, many of the Examiner remarks focus on structure-function correlation, which has no bearing on the amended claims, which do not recite functional language.

In general, Applicants note that many of the Examiner's remarks in support of the enablement rejection seem more appropriate for a written description rejection, which has already been addressed, above.

New dependent claims 40 and 41 are drawn to a subset of the sequences recited in claim 2, and are enabled for similar reasons. New dependent claims 42 and 43 are drawn to the exemplified sequences are enabled for the additional reason that making and using these sequence was expressly described in the specification.

For at least the foregoing reasons, withdrawal of the rejection is respectfully requested.

IV. Rejection under 35 U.S.C. § 112, second paragraph (indefiniteness)

Claims 2-7 and 19-20 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for (i) failing to define "BGL6," (ii) alleged technically incorrect language relating to complementary nucleic acids, and the (iii) use of the phrase "derived from."

Claim 2 has been amended to identify BGL6 as a β -glucosidase. Note that the terms "*bg/6*" and "BGL6" are descriptive in that they refers to a particular β -glucosidase gene and its product, respectively. The terms have no special meaning that the skilled person would need to understand the claims.

Claim 2 has been amended to delete part (h), which included the "complementary" language that was the subject of the rejection. Similar subject matter is now presented in new independent claim 39, which does not included the "complementary" language that was the subject of the rejection.

Claims 6, 7, and 8 have been amended to delete the language "derived from."

None of the rejections are applicable to new dependent claims 40-43.

In view of the amendments, withdrawal of the rejections is respectfully requested.

IV. Rejection under 35 U.S.C. § 102

Claims 2-7, 19, and 20 were rejected under 35 U.S.C. § 102 as allegedly anticipated by Li *et al.* (USPN 6,184,018) or Fowler *et al.* (USPN 6,002,725). The rejection is based on the Examiner's construction of claims to read on di or tri-nucleotides. The Examiner indicated that deleting the fragment language would address the rejection.

Claim 2 has been amended to delete the fragment language. The rejection is not applicable to the newly added claims. Withdrawal of the rejection is respectfully requested.

Although not related to the substance of the rejection, Applicants point out that claim 2(h) and not claim 1(h) (now canceled) originally included the fragment language that was the subject of the rejection. In addition, USPN 6,002,725 relates to a M-ary FSK receiver, and is likely not the patent intended to be cited against the present claims.

V. Double Patenting Rejection

Claims 1-17, 19, and 20 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of USPN 7,045,322.

The rejection is traversed.

USPN 7,045,322 is not co-owned by the present Applicants or their Assignee, does not relate to common subject matter, and does not have five claims. The three claims allowed USPN 7,045,322 relate to a process for producing a lysosphingolipid by using a sphingolipid ceramide N-deacylase.

Applicants assume the rejection was in error and request its withdrawal.

V. Conclusion

Applicants believe the pending claims are fully in condition for allowance. Issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 846-7500. The Commissioner is authorized to charge any fees that may be required in connection with this submission and to credit any overpayments to Deposit Account No. 07-1048.

Respectfully submitted,

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/Stephen Todd/
Stephen Todd
Registration No. 47,139

Danisco US Inc.,
Genencor Division
925 Page Mill Road
Palo Alto, CA 94304
Tel: 650-846-7500
Fax: 650-845-6504